K955829

**II 510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90**

NOV 18 1997

B. Braun Medical, Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
(610)691-5400

December 11, 1995

CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: SafPace™ System

TRADE NAME: Wedge Pressure Catheter with Temporary Transluminal Pacing Wire.

CLASSIFICATION NAME:
Cardiovascular
Class II ,74 LDF, Temporary Pacemaker Electrode
21 CFR 870.3680

SUBSTANTIAL EQUIVALENCE[1] TO:

| 510(k) number | Name | Applicant |
|---|---|---|
| K803058 | Swan-Ganz Flow Directed Catheter | American Edwards Laboratories |
| K923551 | VascoStim | Vascor Medical Corporation |
| K822806/A | Balloon Wedge Pressure, Angiographic and Pacing Catheters | formally; Nova Medical Specialties now a division of B. Braun Medical Inc. |

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

DEVICE DESCRIPTION:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce SafPace™ System. The SafPace™ System is a two part system consisting of a Monitoring/Wedge Pressure Catheter and a Temporary Transluminal V- Pacing Wire. The catheter is designed for accurate measurement of cardiac output, direct measurement of pulmonary artery blood temperature, pressure monitoring, and infusing solutions. The SafPace™ catheter may also be used for temporary ventricular pacing. The V-Pacing Wire is used for temporary ventricular pacing only when used with the SafPace™ catheter. The wire may also be used for intraventricular ECG monitoring.

MATERIAL:

The SafPace™ System is composed of materials which have an established history of medical use and that have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

SUBSTANTIAL EQUIVALENCE:

The SafPace™ System is equivalent in materials, form, and intended use to the Swan-Ganz Flow Directed Catheter currently marketed by American Edwards Laboratories and the Pacing Catheter currently marketed by Nova Medical. There are no new issues of safety or effectiveness raised by the SafPace™ System.

SAFETY AND EFFECTIVENESS:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1997

Mr. Mark S. Alsberge
B. Braun Medical Inc.
824 12th Avenue
Bethlehem, Pennsylvania 18018-0027

Re: K955829
Safpace™ System
Regulatory Class: II (two)
Product Code: LDF
Dated: August 4, 1997
Received: October 29, 1997

Dear Mr. Alsberge:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health